Form: TH-07



Periodic Review and Exempt Action or Exempt Agency Final Regulation Agency Background Document

Agency Name:	Agriculture and Consumer Services
VAC Chapter Number:	2 VAC 5-600
Regulation Title:	Regulations Pertaining to Food For Human Consumption
Action Title:	Amend
Date:	July 7, 2000

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation which is exempt from the Administrative Process Act pursuant to § 9-6.14:4.1.

Note that agency actions exempt pursuant to § 9-6.14:4.1 do not require filing with the Registrar a Notice of Intended Regulatory Action or at the proposed stage. The agency must still, however, comply with the requirements of the Virginia Register Act (§ 9-6.18 et seq. of the Code of Virginia) and file with the Registrar and publish their final regulation in a style and format conforming with the Virginia Register Form, Style and Procedure Manual. The agency must also comply with Executive Order Fifty-Eight (99) which requires an assessment of the regulation's impact on the institution of the family and family stability.

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

This regulation is the adoption by reference of certain provisions of Title 21 and Title 40 of the Code of Federal Regulations. The provisions adopted from Title 21 pertain to human foods. The provisions adopted from Title 40 are those provisions for tolerances and exemptions from the

tolerances for pesticide chemicals in or on raw agricultural commodities and those tolerances for pesticides in foods.

Basis

Form: TH-07

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The legal authority for this regulation is contained in §3.1-398 of the Code of Virginia (1950), as amended. The Code provides that the Commissioner of Agriculture and Consumer Services may adopt any regulation under the federal Food, Drug and Cosmetic Act without public hearing. Such regulation becomes effective upon filing with the Registrar of Regulations, and the Board of Agriculture and Consumer Services, at its next regular meeting, then adopts the regulation after notice but without public hearing. This authority is discretionary. Since adoption of the regulation is by reference, all provisions in the regulation exactly duplicate the federal regulation referenced, thus further contributing to uniform application and enforcement of food safety requirements between the U.S. Food and Drug Administration and the Virginia Department of Agriculture and Consumer Services.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

The Department published its notice in The Virginia Register of Regulations on April 10, 2000 advertising the opportunity to comment on this regulation, pursuant to Executive Order Number Twenty-five (98). There were no public comments received relating to this regulation. An informal advisory group was not formed for the purpose of assisting with this periodic review.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has

determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected. Please state the reasons the agency determined the regulation be amended or terminated.

Form: TH-07

This regulation strengthens the provisions of the Virginia Food Laws that ensure a safe, wholesome, unadulterated and properly labeled food supply. This regulation is effective in achieving these specific and measurable goals.

The agency has determined that this regulation is essential to protect the health of citizens. The regulation establishes Good Manufacturing Practices (GMPs) for food products, which provide requirements for the safe production, processing, storage and distribution of those food products. Failure to follow these requirements can result in situations where foods may become injurious to health. The regulation also identifies standards of identity for certain food products, many of which contain specific production procedures that are intended to preclude adverse health consequences.

Additionally, the regulation contains provisions for the safe use of food and color additives. These production aids can facilitate the manufacture of food products, extend their shelf life and add to their acceptability. However, improper use of these additives can result in food products which are harmful; this regulation identifies the controls under which such additives can be safely used.

This regulation also specifies tolerances for pesticide residues on or in foods. Pesticide residues in food products are a major concern of citizens. The tolerances set by this regulation reflect the best science available concerning safe levels of these chemicals. Levels of these chemicals that exceed the tolerances set by the regulation may contribute to adverse health effects to citizens.

The regulation is clearly written and easily understandable.

The agency has determined that the regulation be amended in order to incorporate changes made to the Code of Federal Regulations since the regulation was last amended in 1991.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The first alternative is to have no regulation. The agency rejects this alternative. In the absence of regulation, food safety will be compromised. Also, it is likely that the Food and Drug Administration would assert its authority and enforce all applicable federal regulations.

The second alternative is to have a regulation governing food for human consumption that selectively adopts federal regulations by reference. The agency endorses this approach because: (1) it allows the agency to adopt those portions of the federal regulations which are least burdensome and enables interstate commerce; and (2) certain provisions of the federal regulation are not applicable to Virginia, and therefore are excluded from the adoption process.

Statement of Final Agency Action

Form: TH-07

Please provide a statement of the final action taken by the agency .including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

The Commissioner of Agriculture and Consumer Services adopted the amended regulation on May 23, 2000.

Additional Information

Please indicate that the text of the proposed regulation, the reporting forms the agency intends to incorporate or use in administering the proposed regulation, a copy of any documents to be incorporated by reference are attached.

Please state that the Office of the Attorney General (OAG) has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law. Note that the OAG's certification is not required for Marine Resources Commission regulations.

If the exemption claimed falls under § 9-6.14:4.1(C) (4)(c) of the APA please include the federal law or regulations being relied upon for the final agency action.

The text of the final regulation is attached. The reporting forms were included with the regulation when it was published in The Virginia Register of Regulations on June 19, 2000, on pages 2458-62 of Volume 16, Issue 20. The forms which are on pages 2460-62 can be accessed at http://legis.state.va.us/codecomm/register/copies.htm. The documents incorporated by reference are federal regulations. It is not necessary to file federal regulations incorporated by reference, pursuant to the Virginia Register Form, Style and Procedure Manual. The Office the Attorney General certified on May 17, 2000, that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Family Impact Statement

Please provide a preliminary analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulation strengthens the authority and rights of parents in the education, nurturing and supervision of their children; encourages economic self-sufficiency, self-pride and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; strengthens the marital commitment; increases disposable family income; and has a positive impact on family formation, stability and autonomy by insuring that food offered for sale, manufactured, processed or stored in Virginia is free from adulteration, properly labeled and honestly advertised for all of Virginia's citizens; and by providing a level playing field in which Virginia's food industries can compete, effecting approximately ten percent* of Virginia's citizens who are involved in the production, processing and distribution of food.

Form: TH-07

*Virginia Agriculture – Economic Contributions & Impact - May, 1998 Virginia Department of Agriculture and Consumer Services